

## REMARKS

### Amendments to the Claims

Claims 4-8, 45-49, 51-53, 55, 57-63, 96-122, 126-146, 149-168 and 170-211 are pending. The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 5, 6, 114, 116 and 117 were amended. The Applicant hereby states that the amendments to the claims do not add new subject matter to the specification.

### Claim Objection

The Examiner has objected to Claim 114 because the claim lacked a period at the end of the sentence. Currently amend Claim 114 contains a period. Therefore, the Applicants respectfully request withdrawal of the claim objection against Claim 114.

### Summary of Interview Pursuant to 37 C.F.R. § 1.133(b)

The Applicants wish to thank the Examiner for the telephone interview on October 4, 2006. Pending claims 102-109 were discussed in view of the outstanding rejection alleging anticipation pursuant to 35 U.S.C. § 102(e). In addition, both parties discussed the sequence restriction requirement pursuant to 35 U.S.C. § 121.

### ***Rejection Pursuant to 35 U.S.C. §102 (e) Anticipation***

The Examiner and Applicants agreed that James J. Schmidt and Robert G. Stafford, *High Throughput Assays for the Proteolytic Activities of Clostridium Neurotoxins*, U.S. Patent 6,762,280 (priority filing date Sep. 25, 2000), hereafter "the Schmidt patent," was not an anticipatory reference. The Schmidt patent discloses two types of substrates called Type I and Type II, see abstract.

The Type I peptide substrates disclosed in the Schmidt patent are useful for quench release assays, see, e.g., col. 4, lines 14-17; and col. 5, line 8 through col. 6, line 59. The Schmidt

patent teaches that both the donor fluorophore and the acceptor need to be located within Arg191 to Met202 of SNAP-25, see, e.g., col. 6, lines 54-67; see also, pp. 13-14 from the October 11, 2005 Applicants Reply. This region corresponds to amino acids 191 to 202 of SEQ ID NO: 2. Claim 102, and the claims depending from this independent claim, is directed towards a BoNT/A substrate where the donor fluorophore, the acceptor, or both the donor fluorophore and the acceptor is not positioned within amino acids 191 to 202 of SEQ ID NO: 2. Thus, both the Examiner and Applicants agreed that the Schmidt patent does not anticipate the presently claimed substrate because this patent teaches that both the donor fluorophore and acceptor of a Type I substrate must be positioned within amino acids 191 to 202 of SEQ ID NO: 2.

The Type II peptide substrates disclosed in the Schmidt patent, of which the peptides SEQ ID NO: 11 and SEQ ID NO: 12 belong, are useful in a fluorescence-release assay, see abstract. The Type II substrates have only a single fluorophore, see, e.g., col. 8 lines 1-49. As such, the Type II substrate of the Schmidt patent comprises only a single molecule capable of emitting light at a certain wavelength. The Type II substrate lacks an acceptor, i.e., a molecule capable of absorbing light from, and upon excitation of, a donor fluorophore. Claim 102, and the claims depending from this independent claim, is directed towards a BoNT/A substrate comprising a donor fluorophore and an acceptor. Thus, both the Examiner and Applicants agreed that the Schmidt patent does not anticipate the presently claimed substrate because this patent teaches that a Type II substrate only has a single fluorophore and does not have an acceptor.

Therefore, the Examiner and Applicants agreed that the rejected claims are not anticipated by the Schmidt patent and the Examiner agreed to withdrawal of the 35 U.S.C. §102(e) anticipation rejection for Claims 102-109.

#### ***Sequence Restriction Requirement Pursuant to 35 U.S.C. § 121***

The Examiner and the Applicants agreed that the all sequences currently claimed will not be withdrawn from consideration from the pending application. SEQ ID NO: 94 will not be withdrawn from consideration because this peptide has the same amino acid sequence as

SEQ ID NO: 91, differing only in donor fluorophore and acceptor. Likewise, SEQ ID NO: 95 will not be withdrawn from consideration because this peptide has the same amino acid sequence as SEQ ID NO: 92, differing only in donor fluorophore and acceptor. SEQ ID NO: 27, SEQ ID NO: 85, SEQ ID NO: 88, SEQ ID NO: 89 will not be withdrawn from consideration because these peptides do not result in any additional searching burdens for the Examiner since these peptides are inclusive of, or extensively identity with, the amino acid sequences of SEQ ID NO: 1, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 90, SEQ ID NO: 91, SEQ ID NO: 92, and SEQ ID NO: 93. Peptides sequences 137-206 of SEQ ID NO: 2 and 134-206 of SEQ ID NO: 2 will not be withdrawn from consideration because these peptides do not result in any additional searching burdens for the Examiner since these two peptides are inclusive of SEQ ID NO: 2.

Therefore, the Examiner and Applicants agreed that SEQ ID NO: 27, SEQ ID NO: 85, SEQ ID NO: 88, SEQ ID NO: 89, SEQ ID NO: 94, SEQ ID NO: 95, 137-206 of SEQ ID NO: 2 and 134-206 of SEQ ID NO: 2 will not be withdrawn from consideration from the pending application.

#### **Rejection Pursuant to 35 U.S.C. § 112, ¶ 1 Written Description**

The Examiner has rejected Claim 116 as allegedly lacking written description under 35 U.S.C. § 112, ¶ 1 because the present specification does not recite "DANCYL." The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

Currently amended Claim 116 recites "DABCYL." Support for "DABCYL" can be found throughout the present specification, e.g., at pg. 20, ¶ 3; pg. 40, ¶ 1; pg. 47, ¶ 2; pg. 53, ¶ 2; pg. 58, ¶ 1; pg. 60, ¶ 1; pg. 62, ¶ 2; pg. 65, ¶ 1; pg. 66, ¶ 2; pg. 84, ¶ 2; pg. 90, ¶ 1; pg. 111, ¶ 1; and Table 6. Therefore, the Applicants respectfully submit that there is adequate written description support for "DABCYL" and respectfully request withdrawal of the 35 U.S.C. § 112, ¶ 1 written description rejection against Claim 116.

**Rejection Pursuant to 35 U.S.C. § 112, ¶ 2 Definiteness**

The Examiner has rejected Claim 117 as allegedly being indefinite under 35 U.S.C. § 112, ¶ 2 because the Claim 117 recites a trademark without accompanying generic terminology. The Applicants respectfully ask for reconsideration under for reconsideration under 37 C.F.R. § 1.111.

Currently amended Claim 117 does not recite the trademark item. Therefore, the Applicants respectfully submit that Claim 117 is clear and precise and request withdrawal of the 35 U.S.C. § 112, ¶ 2 indefinite rejection.

**Rejection Pursuant to 35 U.S.C. § 102 (e) Anticipation**

The Examiner has rejected Claims 102-109 as allegedly anticipated under 35 U.S.C. § 102(e) by the Schmidt patent. Specifically, the Examiner contends that the peptides SEQ ID NO: 11 and SEQ ID NO: 12 disclosed in the Schmidt patent anticipate the peptides set forth in Claims 102-109 because Claim 102 only recites one fluorophore, a donor fluorophore. The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

According to *MPEP* § 2131, for a reference to anticipated a pending claim, that reference must either expressly or inherently teach each and every element of the pending claim.

For the reasons outlined in the Summary of Interview section, both the Schmidt patent does not anticipate Claims 102-109. Therefore, the Applicants respectfully submit that the pending claims are not anticipated by the Schmidt patent and respectfully request withdrawal of the 35 U.S.C. § 102(e) anticipation rejection for Claims 102-109.

### **CONCLUSION**

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. Should there be any questions, the Examiner is invited to call the undersigned agent. Please use Deposit Account 01-0885 for the payment of any extension of time fees under 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

/Dean G. Stathakis/

Dean G. Stathakis, Ph.D.  
Registration No. 54,465  
Agent of Record



**ALLERGAN**

**LEGAL DEPARTMENT**

2525 Dupont Drive  
Irvine, California 92612-1599  
Tel: 714/246-6521  
Fax: 714/246-4249